APR 1 8 2001

K010810

1 OF 2

Summary of Safety and Effectiveness

NAME OF SPONSOR:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) CONTACT:

Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
Phone: (219) 371-4907
FAX: (219) 371-4987

TRADE NAME:

DePuy Preservation Unicondylar Knee Prosthesis

COMMON NAME:

Unicompartmental Knee Prosthesis

CLASSIFICATION:

888.3530 Knee joint, femorotibial metal/polymer semi-constrained cemented prosthesis

DEVICE PRODUCT CODE:

87 HRY

SUBSTANTIALLY EQUIVALENT DEVICE:

PFC Sigma Uni-Compartmental Knee System (K954481)

DEVICE DESCRIPTION:

The DePuy Preservation Unicondylar knee system consists of a Co-Cr-Mo femoral and all polyethylene tibial components. The DePuy Preservation Unicondylar femoral component has a single fixation peg, with circumferential groove, and central keel. The fixation surface of the DePuy Preservation Unicondylar all polyethylene tibial component consists of a grooved single keel, that runs anterior-posterior and is designed to grout the keel into the bone cement.

The DePuy Preservation Unicondylar femoral and tibial components are available in 5 sizes with the all polyethylene tibial component available in three thicknesses, 7, 9.5 and 11.5mm. All five all polyethylene tibial component sizes are designed to articulate with all sizes of the femoral components.

Summary of Safety and Effectiveness (Continued)

INDICATIONS FOR USE:

The DePuy Preservation Unicondylar Knee is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Caution: This knee prosthesis component is intended for cemented use only. Candidates for unicondylar knee replacement include elderly patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. In candidates for unicondylar knee arthroplasty, only one side of the joint (the medial or lateral compartmental) is affected. Unicondylar knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total unicondylar knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

SUBSTANTIAL EQUIVALENCE:

The fundamental scientific technologies of the DePuy Preservation Unicondylar Knee Prosthesis have not changed from the FDA cleared PFC Sigma Uni-Compartmental Knee System (K954481). They have the same intended use, indications, materials, sterilization method, packaging, method of manufacture, and similar designs. DePuy believes that the DePuy Preservation Unicondylar Knee Prosthesis is substantially equivalent to the FDA cleared PFC Sigma Uni-Compartmental Knee System (K954481).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Ms. Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K010810
Trade Name: Depuy Preservation Unicondylar Knee System
Regulation Number: 888.3530
Regulatory Class: II
Product Code: HRY
Dated: March 16, 2001
Received: March 19, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010810

Device Name: DePuy Preservation Unicondylar Knee System

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010810

Prescription Use X OR Over-The-Counter Use_____ (Per 21 CFR 801.109)